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10/575,063

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Robert J Harman

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC

701 FIFTH AVE

SUITE 5400

SEATTLE, WA 98104

EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

08/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/575,063 | Applicant(s) HARMAN ET AL. | |
| | Examiner Lora E. Barnhart | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,20-23,32,37,38,80 and 96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,20-23,32,37,38,80 and 96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/28/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 6/8/09 to claim 20 have been entered. Claims 48, 51, 55, 59, 114, 119, and 128 have been canceled in this reply. No claims have been added. Claims 1-3, 20-23, 32, 37, 38, 80, and 96 remain pending in the current application.

Election/Restrictions

Applicant's election of Group I, claims 1-3, 20-23, 32, 37, 38, 80, and 96, in the reply filed on 6/8/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant canceled all non-elected claims in the instant reply Examination on the merits will commence at this time on the remaining claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 20-23, 32, 37, 38, 80, and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 requires separating cells in adipose tissue from "other tissue components," a phrase that is unclear because it does not particularly indicate which components of adipose tissue are considered "other." It is not clear whether "cells

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therein” at line 4 refers to all of the cells in adipose tissue or to some desired subpopulation. Similarly, lines 7-8 require that the method not require isolating stem cells from “other purified cells,” but it is not clear whether these “other purified cells” were originally present in the adipose tissue or elsewhere. Clarification is required. Independent claims 21, 32, 80, and 96 suffer similar deficiencies. Because claims 2, 3, 20, 22, 23, 37, and 38 depend variously from indefinite claims 1, 21, and 32 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 2 recites the term “fibroblast-like cells,” which is confusing because it is not clear how similar a cell must be to a fibroblast to be encompassed by this limitation. Clarification is required. Claim 22 suffers similar deficiencies.

Claim 3 refers to “extracellular matrix polypeptides or fragments thereof,” but it is not clear whether a “fragment” can include, e.g. a single amino acid that is contained within the full-length polypeptide. Clarification is required. Claim 23 suffers similar deficiencies.

Claim 20 refers to the “tail head region” of the patient, which does not appear to be a term of art. Furthermore, it is not clear how this term relates to tailless patients, e.g. most humans. Independent claim 21 also recites this term, and it is indefinite in that claim for the same reasons. Clarification is required. Because claims 22 and 23 depend from indefinite claim 21 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

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Claim 80 requires contacting tissue with "a series of screens," but it is not clear whether this limitation refers to physical mesh screens or to screening methods.

Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 20-23, 32, 37, 38, and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Zuk et al. (2001, *Tissue Engineering* 211-228; reference AR on 4/28/09 IDS). This rejection addresses embodiments in which the term “separate cells therein” is interpreted as "separate at least some cells therein," and in which “other tissue components” may include mature adipocytes.

Zuk teaches isolating human adipose tissue, washing with saline, and digesting the extracellular matrix within the tissue with collagenase (page 212, last paragraph). Zuk teaches neutralizing the collagenase and centrifuging the resulting mixture to yield a pellet of adipose tissue stromal-vascular fraction (SVF; page 212, last paragraph et seq.). Zuk teaches lysing contaminating red blood cells (which are “other tissue components”), then collecting the remaining SVF and passing it through a nylon mesh to remove cellular debris (page 213, first paragraph). Zuk teaches incubating the filtered SVF overnight in plates (a “container” as in claim 32), then washing it, yielding processed lipoaspirate (PLA; page 213, first paragraph).

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Zuk teaches that SVF contains mast cells, endothelial cells, pericytes, fibroblasts, and preadipocytes in addition to the stem cell fraction in PLA (page 217, paragraph 3). Zuk teaches that PLA is approximately 25% endothelial cells and 29% smooth muscle cells, in addition to mesenchymal cells including MSCs (page 217, paragraph 4). Therefore, both the SVF and the PLA yielded by the methods of Zuk constitute "purified cell populations comprising stem cells," and the methods of Zuk do not isolate stem cells from other purified cells, since SVF and PLA are mixed populations.

The term "tail head region" in claims 20 and 21 does not appear to clearly limit the claims as they pertain to humans, as discussed above. Regarding claim 96, Zuk teaches that serum promotes adhesion of cells, including mesenchymal stem cells (MSCs) present in lipoaspirate, to culture dishes (page 215, last paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 80 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zuk et al. (2001, *Tissue Engineering* 211-228). This rejection addresses embodiments in which the term "separate cells therein" is interpreted as "separate at least some cells therein," and in which "other tissue components" may include mature adipocytes. Furthermore, "screens" is interpreted as physical mesh screens.

Zuk teaches isolating human adipose tissue, washing with saline, and digesting the extracellular matrix within the tissue with collagenase (page 212, last paragraph). Zuk teaches neutralizing the collagenase and centrifuging the resulting mixture to yield a pellet of adipose tissue stromal-vascular fraction (SVF; page 212, last paragraph et seq.). Zuk teaches lysing contaminating red blood cells (which are "other tissue components"), then collecting the remaining SVF and passing it through a nylon mesh to remove cellular debris (page 213, first paragraph).

Zuk teaches that SVF contains mast cells, endothelial cells, pericytes, fibroblasts, and preadipocytes in addition to the stem cell fraction in PLA (page 217, paragraph 3). Zuk teaches that PLA is approximately 25% endothelial cells and 29% smooth muscle cells, in addition to mesenchymal cells including MSCs (page 217, paragraph 4). Therefore, both the SVF and the PLA yielded by the methods of Zuk constitute "purified cell populations comprising stem cells," and the methods of Zuk do not isolate stem cells from other purified cells, since SVF and PLA are mixed populations.

Zuk does not teach contacting the tissue with more than one screen.

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It is well held that duplicating a method step is *prima facie* obvious; see M.P.E.P. § 2144.04. Therefore, it would have been obvious to pass Zuk's SVF through more than one mesh screen in order to remove more cellular debris. M.P.E.P. § 2144 recites, "The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law...If the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court." In *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946), the court found that selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

No claims are allowed. No claims are free of the art.

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, **not** the published application. Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims and share an inventor or assignee with the instant application. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651